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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,541	03/01/2002	Benjamin R. Halpern	ABIOS.022A	2245
22896	7590	09/12/2005	EXAMINER	
MILA KASAN, PATENT DEPT. APPLIED BIOSYSTEMS 850 LINCOLN CENTRE DRIVE FOSTER CITY, CA 94404			BORIN, MICHAEL L	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 09/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/087,541

Applicant(s)

HALPERN, BENJAMIN R.

Examiner

Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2005.
2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
4a) Of the above claim(s) 1-7 and 11 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 8-10 and 12-19 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2 IDSs.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 16-19 are added. Claims 1-19 are pending.

Response to restriction requirement filed 06/20/2005 is acknowledged. Applicant elected, without traverse, Group III, claims 8-10, together with amended claims 12-15 and added claims 16-19. Claims 1-7, 11 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected groups.

Information Disclosure Statement

2. Applicants' Information Disclosure Statements filed 08/25/2003 and 11/04/2003 have been received and entered into the application. Accordingly, as reflected by the attached completed copies of forms PTO-1449, the cited references have been considered.

Claim Rejections - 35 USC § 112, second paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 8-10, 12-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is applied for the following reasons:

- A. Step (c) of the base claim 8 is detected to determining a spectral range for modified query peptide. Specification teaches that spectral range is the range from zero to the unmodified query peptide's mass, but does not provide method steps for "determining " the spectral range.
- B. Claim 17: The term "selected comparison" is not clear. Specification does not teach what constitutes a "selected" comparison .

Claim Rejections - 35 USC § 112, first paragraph.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 9,10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claim 9 introduces new matter by using phrase "excluding modified mass values during the comparison of the modified query peptide to the library of database peptides". The specification does mention excluding modified query masses from comparison with the peptide index not database peptides – see paragraph [0075]. "Peptide index" is clearly different from "peptide database" – see paragraph [0048]. Alternatively, specification discusses excluding the "difference mass", the latter being not the same as "modified mass" addressed in the claim language.

Similarly, claim 10 introduces new matter by using phrase "adjusting ... during the comparison". The specification does not teach adjustment in the course of comparison.

Claim Rejections - 35 USC § 102.

The following is a quotation of the appropriate paragraphs of 35 U.S.C.102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 8-10,12-19 are rejected under 35 U.S.C. 102(b) as anticipated by Wilkins et al.(J. Mol. Biol. (1999) 289, 645-657) or under 35 U.S.C. 102(e) as anticipated by Eriksson et al (US Patent 6,466,010).

The instant claims are drawn to method for comparing a modified query peptide to a plurality of database peptides. "Modified" means polypeptide modified by any post-translational modification, such as phosphorylation, oxidation, substitution, etc, which alters mass of the query polypeptide. The claimed method comprises the steps of: (a) generating a plurality of query mass values for said query peptide; (b) identifying modified mass values from said plurality of query mass values; (c) determining a

spectral range for said query peptide; (d) subdividing said spectral range into a plurality of equal intervals; (e) performing a plurality of searches on said plurality of equal intervals. A spectral range is the range from zero to the unmodified query peptide's mass.

Wilkins et al teach a method of identifying of protein post-translational modifications. A protein (i.e., a query polypeptide) suspected of being modified is subjected to fragmentation (i.e., subdivided into plurality of mass intervals), and fragments are subjected to mass-spectrometry (i.e., which generates a plurality of query mass values for said query polypeptide). The fragments that do not match any unmodified peptides in a protein database (i.e., by performing plurality of searches), within a preset tolerance value in its prediction, are identified as "modified" (i.e., identifying modified mass values from said plurality of query mass values). Twenty two post-translational modifications considered include acetylation, amidation, hydroxylation, lipoylation, methylation, myristoylation, N-acyl diglyceride (tripalmitate), O-GlcNAc, phosphorylation, pyridoxal phosphate, sulphation, etc. The nature of modification is determined and thus the nature of the fragment can be corrected and thus the identity of the query polypeptide can be determined. See abstract, p. 646, right column, pages 652 through 656. Further, the user first identifies unmodified fragments and then proceeds with identifying modified fragments (p. 646, right column); thus excluding modified mass values at the first step of comparing (compare to claim 9).

Eriksson et al (US Patent 6,466,010) teaches method for assessing significance of protein identification. The method comprises steps of generating mass data for fragments of a query polypeptide (e.g., claim 1) wherein the polypeptide may have post-translational modifications (see col. 9, lines 42-44; claim 28) and compared to protein database, wherein the database comprises information on polypeptides which exhibit modifications. The query polypeptide is cleaved into a parts by a method that produces constituent parts in a predictable way (claim 42), and comparison can be constrained within a chosen mass range (claims 45, 47)

It is the Examiners position that all the elements of Applicant's invention with respect to the specified claims are instantly disclosed or fully envisioned by the teaching of the references cited above

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

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patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claim 8-10,12-19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 10/241751. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of 10/241751 are directed to method for comparing a modified query peptide to a plurality of database peptides, the method comprising: generating a plurality of query mass values for the query peptide; generating a plurality of database mass values associated with the plurality of database peptides; identifying a modified set of query mass values from the plurality of query mass values wherein the modified set of query mass values correspond to mass values that reflect a modification to the query peptide; adjusting the plurality of query mass values associated with the modified set of query mass values to account for mass differences resulting from the modification to the query peptide, and performing a comparison search which compares the plurality of adjusted query mass values to the plurality of database mass values to thereby associate the query peptide with at least one database peptide.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Prior art made of record

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Patterson et al review a variety of methods of mass spectrometric approaches for identification of post-translational modifications in peptides which are also readable on the instantly claimed method. Clauser et al. teach method of identifying modified peptides. Yates et al (US Patent 5,701,256) teaches method for correlating a mass spectrum of a peptide fragments with database of sequences.

Conclusion.

8. No claims are allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Michael Borin, Ph.D.
Primary Examiner
Art Unit 1631

mlb